

AUG 10 2005

K 050824

1/4

510(k) Summary
100W Ceralas Diode 980 nm Laser System (Model D100)

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.
Date prepared: March 31, 2005

Name of Device and Name/Address of Sponsor
Ceralas D980 Diode Laser System, Model D100 ("100W Ceralas D980")

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name
Diode laser

Predicate Devices
50W Ceralas D 980 Diode Laser System and Ceralas F100 Nd:YAG Laser System

Intended Use/Indication for Use

The device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures including via endoscopes. The device is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary and cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps

- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Menisectomy
- Synovectomy
- Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and homeostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis

- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangiectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and homeostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia

Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: homeostasis in conjunction with meningiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

Dental Applications

Indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use with the ELVes Procedure Kit in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Technological Characteristics

The 100W Ceralas D 980 is identical to the previously cleared 50W Ceralas D 980 except for four modifications. The 100W Ceralas D 980 has a maximum wattage of 100W, while the cleared 50W Ceralas D890 has a maximum wattage of 50W. In addition, the 100W Ceralas D980 has a beam divergence of 12.7°, rather than 20.5°, and therefore can be used with delivery fibers of smaller diameter (0.22 NA or greater) than those recommended for use with the 50W Ceralas D 980 (0.37 NA or greater). Finally, the 100W Ceralas D 980 contains additional diodes.

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 601-1; IEC 601-2-22; EN 60825-1, and ANSI/AAMI/ISO 10993-7.

Substantial Equivalence

The 100W Ceralas D 980 has the same intended use and the same general and specific indications for use as the cleared 50W Ceralas D 980 Laser System. It also has the same intended use and some of the same general indications for use as the cleared 100W Ceralas Nd:YAG Laser System. The four minor technological modifications to the cleared 50W Ceralas D980 incorporated into the 100W Ceralas D 980 -- the increase in maximum wattage from 50W to 100W and in the number of diodes used to generate that wattage and the difference in beam divergence and recommended use with a smaller diameter delivery fiber -- do not raise any new questions of safety or effectiveness. Thus, the 100W Ceralas D 980 is substantially equivalent to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 10 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biolitec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, D.C. 20004-5910

Re: K050824

Trade/Device Name: Ceralas D 980 nm Diode Laser System, Model D100

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: June 28, 2005

Received: June 28, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Mr. Jonathan S. Kahan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Acting Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 050824

Device Name: **Ceralas D 980 nm Diode Laser System, Model D100**

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Division Sign-Off
Division of General, Restorative
and Neurological Devices

Page 1 of 1

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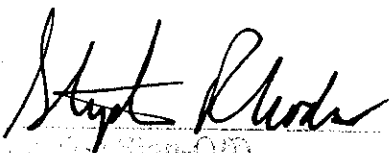
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Page 2 of 4



Signature Sign-Off

Division of General, Restorative

and Neurological Devices

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Number K050824

Gynecology

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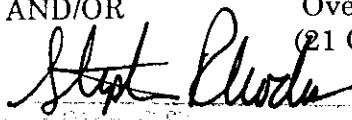
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Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

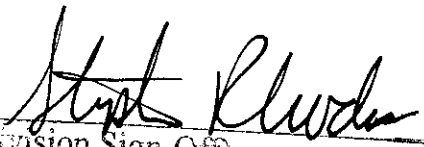
Over-The-Counter Use
(21 C.F.R. 807 Subpart C)


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Page 3 of 4

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PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


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Page 4 of 4

510(k) Number K050824